

REMARKS

Status of the Claims

The non-final Office Action rejects all of the pending claims (Claims 65-71), which were entered following Applicants' Request for Continued Examination (RCE).

Response to Double Patenting Rejection

Claims 65-71 are provisionally rejected for alleged obviousness-type double patenting over Claims 164-186 of Appl. No. 11/116064.

Without accepting the merits of the provisional rejection, Applicants are submitting herewith a terminal disclaimer over the cited application, and therefore respectfully request withdrawal of the rejection.

Response to Anticipation Rejection

Claims 65-71 are rejected under 35 USC § 102(b) over US Patent No. 5750509 to Malabarba et al. ("MALABARBA"). The rejection states that MALABARBA discloses a composition in powder form comprising dalbavancin and a stabilizer, discloses dalbavancin in combination with a sugar such as lactose, that MALABARBA falls within the scope of the present claims, and that Applicants' claims are anticipated.

Applicants respectfully traverse the rejection because the applied art does not disclose each and every limitation of the claims. With respect to Claim 65, MALABARBA does not disclose, *inter alia*, MAG, much less disclose or enable the claimed MAG amounts. Furthermore, Claims 66, 67, and 71 recite still more stringent tolerances.

MALABARBA also does not disclose and the rejection does not assert that MALABARBA discloses, *inter alia*, the pH range recited in Claim 68.

MALABARBA also does not disclose and the rejection does not assert that MALABARBA discloses, *inter alia*, the Bo mole percent recited in Claim 70.

Thus, reconsideration and withdrawal of the rejection are respectfully requested.

Respectfully, contrary to the position taken in the rejection, a lyophilized dalbavancin composition that is not stabilized or pH adjusted had an initial MAG content of 4.5 % and an initial Bo content of 83.6 % by HPLC distribution. Please see US7119061 at Table 7 and Figs. 1-2 (Composition D). Thus, the claimed invention is not disclosed or inherent in MALABARBA.

For at least these reasons, reconsideration and withdrawal of the rejection are respectfully requested.

Response to Obviousness Rejection

Claims 65-71 are rejected under 35 USC § 103(a) over MALABARBA. The rejection states that, in the alternative to anticipation, any differences between MALABARBA and the claims would appear to be minor in nature and that the claims would have been *prima facie* obvious to the skilled artisan.

Applicants respectfully traverse the rejection because the claims are not suggested or obvious in the applied art.

MALABARBA does not render obvious, *inter alia*, the claimed MAG content. There is no dispute that MALABARBA does not expressly disclose MAG. Moreover, as demonstrated above, without effective stabilization as taught by Applicants, the claimed MAG content is not achieved. Claims 66, 67, and 71 recite still more stringent tolerances that also are not suggested or obvious in the applied art. The composition examples in US US7119061 demonstrate that without a combination of both pH adjustment and effective stabilization, the presently claimed MAG contents were not achieved.

MALABARBA also does not render obvious, *inter alia*, the claimed effective stabilizer. MALABARBA, which does not recognize or characterize dalbavancin stability, states that compositions "may contain formulary agents such as suspending, stabilizing and/or dispersing agents." Col. 28, ll. 9-12. However, it is not obvious therein as to what the stabilizer is or may be or how and how much to employ such a stabilizer for success. The reference to lactose in MALABARBA (col. 27, ll. 55) is not relevant or suggestive to the present claims as it is taken from a laundry list of excipients for oral formulations outside the context of stabilization.

MALABARBA also does not render obvious, *inter alia*, the claimed pH range of Claim 68. The rejection does not cite any section of MALABARBA that would allegedly render the claimed pH range obvious. The claimed range of about 3.5 to about 4.5 does not literally encompass pH 3.01.

MALABARBA also does not render obvious, *inter alia*, the claimed Bo content of Claim 70. Once again reference is made to the composition examples in US7119061. The two exemplified compositions that did not contain at least 85 % Bo (Compositions B and D) were not stabilized with a stabilizer. The only composition that did not contain a stabilizer and had a Bo content at least 85 % was pH adjusted to 4.5.

For at least any or all of these reasons, reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

In view of the above, Applicants respectfully submit that the pending claims are allowable in their present form, and that the application is otherwise in condition for

allowance. The Examiner is respectfully requested to withdraw the rejections and to provide a Notice of Allowance.

If any issues remain which can be resolved by a telephone conference, or should the Examiner have any questions or concerns regarding this matter, the Examiner is respectfully invited to contact the undersigned.

Respectfully submitted,

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